



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>4</sup> : A61K 9/08, 9/10, A01N 25/02 A61N 25/04, A61L 15/03		A1	(11) International Publication Number: WO 86/ 05391 (43) International Publication Date: 25 September 1986 (25.09.86)
(21) International Application Number: PCT/AU86/00068 (22) International Filing Date: 13 March 1986 (13.03.86) (31) Priority Application Number: PG 9679 (32) Priority Date: 13 March 1985 (13.03.85) (33) Priority Country: AU (71)(72) Applicant and Inventor: GLUCK, Bruno, Anthony [AU/AU]; 20 King Avenue, Balgowlah, NSW 2093 (AU). (74) Agent: SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU). (81) Designated States: AT (European patent), AU, BE (Eu- ropean patent), BR, CH (European patent), DE (Eu- ropean patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO,		SE (European patent), US. Published With international search report. With amended claims.	
(54) Title: ANTISEPTIC FLUIDS			
(57) Abstract <p>Dual purpose antiseptic fluids, which additionally to being effective skin disinfectants are also capable on drying to form skin protective film with residual antibacterial properties. These antiseptic fluids, while primarily applied as skin disinfectants for pre- and post surgery, dermatological infections, burn treatment as well as first aid for superficial wounds, cuts and abrasions, offer the additional advantage of a temporary or longer lasting skin and wound dressing depending on the film forming polymer used, without impairing the normal physiological activity of the skin. The invention also relates to medical surgical, and veterinary devices in particular to liquid applicators for antiseptic fluids to the human skin for medical, pre- and post surgical applications and first-aid.</p>			

***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GA	Gabon	MR	Mauritania
AU	Australia	GB	United Kingdom	MW	Malawi
BB	Barbados	HU	Hungary	NL	Netherlands
BE	Belgium	IT	Italy	NO	Norway
BG	Bulgaria	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali		
FR	France				

- 1 -

DESCRIPTIONANTISEPTIC FLUIDSTECHNICAL FIELD

The invention relates to dual purpose antiseptic fluids, which additionally to being effective skin disinfectants are also capable on drying to form skin protective film with residual antibacterial properties.

These antiseptic fluids, while primarily applied as skin disinfectants for pre- and post surgery, dermatological infections, burn treatment as well as first aid for superficial wounds, cuts and abrasions, offer the additional advantage of a temporary or longer lasting skin and wound dressing depending on the film forming polymer used, without impairing the normal physiological activity of the skin.

The invention also relates to medical, surgical and veterinary devices in particular to liquid applicators for antiseptic fluids to the human skin for medical, pre-and post surgical applications and first-aid

BACKGROUND ART

Antiseptic fluids are solutions of a substance of known antibacterial properties dissolved in a solvent such as water or a lower alcohol or mixture of both. The bactericidal substance is, after application, deposited directly onto the skin and can through its contact cause to persons known to have hypersensitive skin, or to be allergic, considerable discomfort through reddening, itching or other sensations.

It is desired, after disinfection of the skin prior to or after surgery, open wounds, cuts and abrasions and especially burns, that there is continuous protection against any reinfection provided by residual antibacterial action of the antiseptic fluid employed or by physical means such as the use of closely fitting bandages made from sterilised fabrics or both. Residual bactericidal properties are claimed by some commercially available disinfectants but these can be expected to be only of short duration. For example the residual antibacterial efficiency of the widely used quaternary ammonium compounds as disinfectants is greatly affected by the pH of normal healthy skin and the organic matter contained in its exuding fluids. There is also a reduction of deposited

- 2 -

bactericides due to removal by perspiration. The use of bandages made from various fabrics can be cumbersome, often interfering with the movement of the affected parts of the body, requiring frequent time-consuming changes.

5 In recent years wound dressings for use on superficial burns, cuts and abrasions as well as pre- and post surgical dressings of the skin have been developed, providing a clear plastic film over the affected areas. These plastic wound dressings, often referred to as "plastic bandages" are usually  
10 solutions of an acrylic or methacrylic co-polymer dissolved in a volatile non-aqueous organic solvent of low boiling point such as ethyl acetate, acetone, ethyl alcohol or methylene chloride or mixtures thereof, reducing drying time to a minimum.

15 Although they protect the treated areas through their coherent film formation acting as a physical barrier against outside contamination and possible infection, they have no antibacterial activity and should therefore only be applied after disinfection of the skin. A serious disadvantage of  
20 these liquid bandages is that the non-aqueous solvent for the film forming polymer can cause considerable pain if applied to open wounds, cuts and abrasions. For good adherence, such liquid bandages can only be applied to perfectly dry skin. This makes them less suitable where the skin is contaminated  
25 by body fluids such as blood, strong perspiration or pus. Furthermore, these liquid bandages suffer from the disadvantage that the film consisting of a non-porous water-insoluble polymer closes the pores of the skin hermetically, thus not allowing it to perform its normal  
30 physiological functions. Modifications of such films have been claimed to make them semi-permeable to be better able to cope with the body fluids exuded from the skin.

More recently spray plastic bandages have been described, whereby the polymer is dissolved in an organic  
35 solvent or the propellant itself to form a film on the skin removable by washing with soap and water. A spray bandage is also described in Australian Patent No. 527 826 where the film consisting of a water insoluble polymer such as

polybutylmethacrylate is dissolved in an organic solvent

- 3 -

containing a water soluble bactericide such as a quaternary ammonium compound and bacteriostat such as a chlorinated hydroxydiphenylether. It is claimed that the water soluble bactericide will be leached out from the polymeric film for the immediate disinfection of the skin and that the resulting porous film will subsequently allow sufficient humidity to pass through, for the remaining bacteriostat in its anhydrous medium to exert residual antibacterial activity.

There are also known antiseptic preparations being aqueous solutions of an iodine complex with poly(N-vinyl-2-pyrrolidinone), which after application leaves a film of the iodine complex on the skin. This film formation is only incidental to the disinfecting properties and because of the thinness of the film as it is removed immediately when in contact with moisture, it cannot be regarded as a protective wound dressing.

It is common practice to apply a fluid antiseptic to wounds, cuts, lacerations, burns and skin infections and in surgery before and after incision of the skin. A further widely used practice is to disinfect small skin areas before penetration by a hypodermic needle or insertion of a canule for intravenous feeding or blood transfusion. The area of the skin to be disinfected is customarily either painted with a soft brush, swabbed by means of a swab or sponge made of a soft porous material dipped into an antiseptic fluid. In surgery, swabs are held either by a forcep or are attached to the end of a rigid handle as disclosed in US Patent No. 3 508 547. The antiseptic fluid is held in an open container and the swab dipped into its content, which is discarded after the operation, causing a waste of the larger part which remained unused. Furthermore, the swabs or sponges discarded after use could easily be mistakenly included in the swab count if contaminated with clotted blood or after use with an iodine disinfectant because of similarity of colour.

- 4 -

5     piercing the container prior to application, allowing flow of its content into the applicator sponge. The device is discarded after only one single use. A similar but reusable device is claimed in US Patent No. 3 482 920, where the fluid applicator is held in a retaining ring with a piercing arrangement in the cap for opening the connecting rigid container and thus releasing the contained fluid to flow into the applicator.

10     In another US Patent No. 3 179 972, an applicator top being attached to a connecting bottle is described having a skin contacting surface of a microporous plastic material.

15     Common to all these devices is the fact that they allow only the use of low viscosity fluids capable of flowing freely by gravity alone from the container through the porous applicator on to its surface thus causing, when using the device when still full or nearly full, problems of liquid over-flow and run-off from treated skin areas. Furthermore, as some of the contents is used up and an equilibrium between outside air pressure and pressure inside the container is  
20     established, the antiseptic fluid will cease to flow into the applicator head and the device will have to be discarded with a large part of its content going to waste. There is also the risk, with the reduction of pressure inside the container of less antiseptic fluid flowing into the applicator head, which  
25     in turn, due to insufficient moistening might cause uneven application, leaving some skin areas untreated.

#### DESCRIPTION OF THE INVENTION

30     It has now been discovered that, when a water soluble or partially water soluble bactericide and/or bacteristat is dissolved or dispersed in an aqueous medium which may contain certain amounts of a volatile organic medium, such as ethanol, and a water soluble or water dispersible film forming polymer, on evaporation of the medium sufficient water is retained in the film for the bactericide and/or bacteristat to be  
35     effective. The film itself possesses residual antibacterial

- 5 -

and bacteristats, no adverse, or considerably reduced adverse skin reactions such as reddening of the skin or itching occur, although a dressing containing such agents is left in contact with the skin for many hours.

5       The present invention thus relates to a dual purpose antiseptic fluid which additionally to being a liquid disinfectant for broken and unbroken skin, open wounds, burns, cuts and abrasions, leaves a protective dressing in form of an elastic film over the treated areas with residual  
10       antibacterial properties.

      The dual purpose antiseptic fluid of the invention, after disinfection provides an elastic dressing which does not interfere with the normal physiological activity of the skin and is removable with water or with soap and water.

15       The antiseptic fluid of the invention causes a minimum or irritancy to sensitive skin otherwise caused by the direct contact and deposition of the bactericide and/or bacteristat direct onto the skin.

      The invention also relates to a simple, reusable device  
20       for the application of the antiseptic fluid in an economic and effective manner to surfaces such as skin.

      The invention therefore provides a dual-purpose antiseptic fluid comprising at least one bactericide and/or bacteristat at least one water-soluble or water-dispersable  
25       film forming polymer and water.

      The fluid of the invention may optionally contain a water miscible, non-toxic volatile co-solvent such as a lower alcohol, e.g. ethanol, isopropanol, or the like.

      The use of a slow drying solvent in such antiseptic  
30       fluids allows sufficient time for the active ingredients to act as in any other antiseptic fluid to assure complete disinfection of the treated skin area. It is generally accepted that for efficient skin disinfection, the composition should be in contact with the skin for about 30 to about 90  
35       seconds. For practical purposes however, the drying time of the solvent should be adjusted by the addition of the appropriate quantity of a water miscible volatile co-solvent such as ethanol or isopropanol.

- 6 -

also preferred that the concentration of the active ingredient is sufficient to achieve complete disinfection of the skin during film formation.

For certain purposes the co-solvent content might be raised as high as 70% by volume to reduce drying time to a few seconds only. The additional bactericidal power of co-solvents such as ethanol at this concentration assures asepsis of the skin even within the reduced drying time.

For the more widely used dual purpose antiseptic fluids of the invention, especially those for general household first aid, it is preferred that no unpleasant stinging sensation is experienced on application to broken skin, cuts and abrasions due to too high a content of co-solvent such as ethanol.

For application to burns it might be desired to include a topical local anaesthetic to reduce pain.

A distinct advantage of the dual purpose antiseptic fluid of the invention containing a water-retaining film forming polymer is that after disinfection of the skin, not only residual antibacterial activity is maintained, but that it is directed simultaneously against the outside environment and the skin. Thus, even if a slow acting bacteristat is employed, disinfection of the skin is continued even if the film has been formed before asepsis of the skin has been achieved. There is also the important added advantage that after normal disinfection of the skin the remaining bacterial flora residing in the depth of the skin tissue, often protected by fatty matter, and brought to the surface at a later time by perspiration, is destroyed on contact with the active ingredient in the film. It is therefore an important application of the present invention to provide an "invisible antiseptic glove" as an additional safeguard not only for surgeons' hands under the surgical glove against possible puncturing or cuts of the glove by surgical instruments, but also to serve as a temporary surgical glove for small emergency operations in the field.

The observed reduction and even elimination of skin

- 7 -

understood, as, on dissolving the film forming polymer, a protective colloid is formed around the molecule of the bactericide, and which without interfering with its antibacterial activity is preventing its direct contact with the skin not only during disinfection but even more so once film forming has set in.

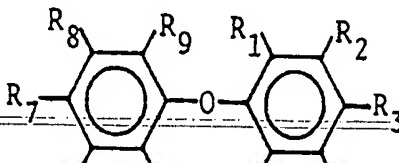
Another advantage of the protective colloid and the film formation around the molecule of the bactericide is that the possible deactivation through organic matter is reduced and residual antibacterial activity is increased. The use of a water soluble polymer has the further advantage that by selecting polymers of sufficient high molecular weight, the viscosity of the antiseptic fluid can be adjusted to be sufficiently high as to avoid unnecessary and annoying run-off after application.

It is advisable to incorporate small amounts of a plasticiser to increase the flexibility of the film. Such plasticisers are for example the polyethylene glycols or a surface active substance such as the nonylphenolpolyethoxy condensates to assure even spreading of the antiseptic fluid on the skin prior to filmformation in emergencies on unwashed skin and those people whose skin is oily or fatty.

The fluids of the invention optionally may contain a moisturiser. This is especially useful to enhance the moisture retaining properties of the polymeric film. Some moisturisers may additionally act as a plasticiser. Examples of suitable moisturisers include glycerol, sorbitol, diethylene glycol, polyethylene glycol 400 and nonionic lanolin derivatives.

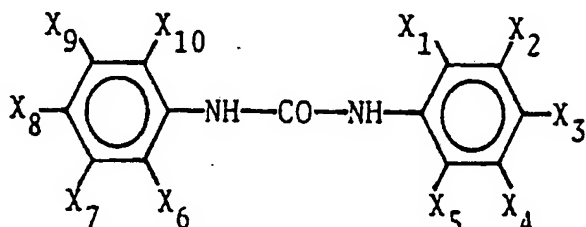
Suitable bactericides and bacteristats which may be employed in compositions of the invention include halogenated hydroxydiphenyl derivatives or halogenated salicyl and carbanilides.

Examples of these bactericides and/or bacteristats are those of the formula

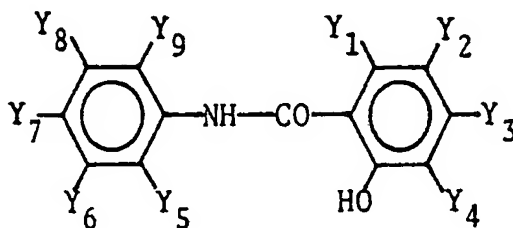


- 8 -

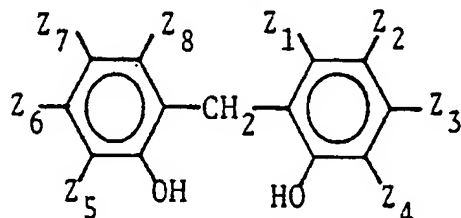
wherein each of  $R_1$  to  $R_9$  may be hydrogen, halogen, lower alkyl, haloloweralkyl, lower alkoxy, allyl, cyano, amino or acetyl and the O-acyl derivatives thereof provided that at least one of  $R_1$  to  $R_9$  is halogen:



wherein each of  $X_1$  to  $X_{10}$  may be hydrogen, halogen, haloalkyl, nitro or alkoxy provided that at least one of  $X_1$  to  $X_9$  is halogen:



wherein each of  $Y_1$  to  $Y_9$  is hydrogen or halogen, provided that at least two of  $Y_1$  to  $Y_9$  are halogen; and



wherein each of  $Z_1$  to  $Z_8$  may be hydrogen or halogen provided that there is at least two halogen substituents on each Phenyl ring.

Such compounds are disclosed in Australian Patents Nos. 200 868, 209 986, 236 460, 273 941, 278 661 and 283 658 and in US Patents Nos. 2 250 840, 2 967 885, 3 254 121, 3 057 920 and 3 064 048.

Examples of the preferred bactericides and/or bacteristats include 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan); 2,2'-dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane systematic name (hexachlorophene); 3,5,4'-tribromosalicylanilide (tribromsalan).

2,4,4'-trichloro- or 2-trifluoromethyl-4,4'-dichloro

- 9 -

chloride and iodine complexes known as iodophors.

The concentration of the active ingredient should be within the range recommended by the manufacturers, and be no different to those used in standard antiseptic solutions.

5 The film forming polymers, which provide films with sufficient water retention to allow for bactericidal bacteristatic activity of the incorporated active ingredients are, for example, methylcellulose, ethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, 10 carboxymethylcellulose and its alkali metal salts and partial salts with 2-aminomethylpropanol, diethylaminopropylamine and triisopropanolamine; copolymers of N-vinyl-2-pyrrolidinone with vinyl acetate, vinyl propionate, crotonic acid, long chain  $\alpha$ -olefins, alkylaminoacrylates and methacrylates; 15 copolymers of vinyl acetate with crotonic acid; terpolymers of N-vinyl-2-pyrrolidinone with vinyl acetate and vinyl propionate, or with vinyl acetate and alkylaminoacrylates or methacrylates; quarternised copolymers of N-vinyl-2-pyrrolidinone and dimethylaminoethyl methacrylate; 20 poly(methyl vinyl ether-maleic anhydride); and polymers having free carbonyl groups.

Most suitable are the film forming polymers containing free carboxyl groups in their molecules, especially in the form of more water soluble salts. On contact of their films 25 with the acid pH of normal skin, these groups are soon reconverted into the original carboxy groups, making the film less soluble by perspiration and outside humidity. They are however easily removed by washing with soap and water, as even the light of alkalinity of normal toilet soaps is sufficient 30 to convert the carboxy groups into their more soluble salt group. Suitable polymers are for example co-polymers of vinyl acetate and crotonic acid, ter-polymers of N-vinyl-2-pyrrolidinone with vinyl acetate and alkylaminoacrylates or methacrylates.

35 Suitable polymers are also methylcellulose

- 10 -

non-running fluids are obtained allowing an even covering of well defined areas of the skin, resulting in a longer lasting antiseptic protective film against post-operative infections, with higher resistance against abrasions when applied under plaster casts and bandages than was hitherto possible to obtain. Where N-vinyl-2-pyrrolidinone is a co-monomer, the co-polymer can be directly complexed with iodine using the poly(N-vinyl-2-pyrrolidinone) component to serve as the iodine carrier.

Similarly, the water soluble alkali metal salts of carboxymethylcellulose can be used in conjunction with other polymeric film forming substances at a pH preferably between 7.0 and 8.0, but not much below pH 6.0. Due to their ionic character care has to be taken in the choice of the bactericides being part of the composition as to their compatibility. Thus they cannot be used in conjunction with cationic substances such as quaternary ammonium compounds.

Suitable examples of substances for partial salt formation of these polymers to render them more hydrophilic or even completely watersoluble are: 2-aminomethylpropanol, diethylaminopropylamine and tri-isopropanolamine.

The dual purpose antiseptic fluids according to this invention are suitably applied by any conventional method such as painting, swabbing or dabbing onto the skin or by means of a suitable applicator.

In a further embodiment, the invention provides apparatus for applying a fluid to a surface, which apparatus comprises a container for said fluid defining a reservoir, an applicator head in fluid communication therewith, fluid flow restricting means between said reservoir and said applicator head, first cap means associated with said container for filling with fluid and second cap means for said applicator head to prevent evaporation of fluid therefrom, wherein said applicator head comprises a resilient porous pad held in a dome shaped cap in contact with said fluid flow restricting means.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a representation of an applicator suitable

- 11 -

Figure 2 is an enlarged cut-away view of the applicator head depicted in Figure 1.

#### MODES FOR CARRYING OUT THE INVENTION

The antiseptic fluids of the invention may be applied by various known means such as spraying, swabbing, dipping, painting and the like.

The fluids may also be applied from an applicator of the type depicted in the drawings. Such an applicator (1) is made up of a reservoir (2) for antiseptic fluid and has an outer cap (3) which may incorporate a clip (4) so that the applicator can be carried securely in a pocket or the like.

The reservoir (2) is closed with a perforated shaped cap (5) covered with a resilient pourous pad (6) and held in place by a collar (7).

The pad (6) is preferably made of a synthetic resilient plastic material such as open polyurthane foam, multilayers of finely woven cotton cloth or absorbent felt. The pad (6) is held over a perforated dome shaped cap (5) clipped in place allowing through flow of the antiseptic fluid. For the cap (5) a rigid plastic material unaffected by the antiseptic fluid is to be selected. Suitable plastic materials are polyvinylchloride, polyethylene and propylene, styrene and similar polymeric materials. The perforation of the cap (5) is such that the pad (6) is evenly moistened, preferably by a number of small symmetrically placed holes. The size of the perforations depending on the viscosity of the fluid is to be such that by inverting the applicator (1) no gravity feed into the pad occurs and a small amount of pressure on the reservoir (2) is needed for the necessary amount of fluid to moisten it. The applicator, when not in use, is hermetically closed by a removable outer cap (3) which either screws or clips on, made of a similar material as the perforated dome-shaped cap (5). This assures that any vapours from the antiseptic fluid cannot escape, thus keeping the pad (6) continuously moist.

This assures the the device not only being protected from

- 12 -

propylen , enabling the antiseptic fluid to flow when inverted into the pad (6) on applying pressure to the side walls. A preferred manner of filling the antiseptic fluid is by way of a flexible bag (not shown) which is connected to the

5 perforated cap (5). In such a case, the semi-rigid reservoir (2) will incorporate an air-vent. Thus, as the antiseptic fluid is withdrawn from the flexible bag, the pressure of the air entering the reservoir (2) provides a continuous delivery of the antiseptic fluid to the pad (6) at the same rate as it

10 is used up. The flexible bag may be made up from any suitable material such as polyethylene or propylene, nylon and the like.

The following examples illustrate preferred embodiments of the invention. They should not be construed as limiting the claims hereto. Unless otherwise indicated, the

15 ingredients are combined by standard cold mixing processes.

In all examples pH adjustments were made with phosphoric acid or an organic acid such as citric or lactic acid or with a mild alkali such as triethanolamine.

EXAMPLE 120 First Aid Disinfectant and Dressing

iodine complex with N-vinyl-2-pyrrolidinone:

vinyl acetate co-polymer, ratio 70:30,

available iodine 10% 5.0g

co-polymer of N-vinyl-2-pyrrolidinone:

25 vinyl acetate, ratio 30:70 5.0g

nonylphenolpolyethoxy(14)condensate 0.1g

ethanol 30.0ml

water, dist to make 100.0ml

The iodine complex of the co-polymer was obtained by

30 using published standard methods for complexing with poly(N-vinyl-2-pyrrolidinone).

EXAMPLE 2First Aid Disinfectant and Dressing

chlorhexidine gluconate 0.05g

35 co-polymer of vinylacetate with

crotonic acid 3.00g

polyethylene glycol 400 0.30g

ethanol 40.00mL

2-aminomethylpropanol 0.24g

- 13 -

The polymer was dissolved by adding it to the solvent mixture containing the chlorhexidine and the polyethylene glycol and sufficient quantity of the 2-aminomethylpropanol added to obtain solution. The pH was kept between 6 to 7.

The composition is suitable to be packed as an aerosol spray, using hydrocarbons as propellant.

### Example 3

#### Antiseptic Prepping Fluid and Dressing

This fluid is useful for disinfection of the skin prior to insertion of a hypodermic needle, canule or general disinfection prior and post surgery:

povidone-iodine containing 10% available iodine	10.0g
co-polymer of N-vinyl-2-pyrrolidinone:	
vinyl acetate, ratio 50:50	10.0g
polyvinylpyrrolidone K 90	2.0g
nonylphenolpolyethoxy(14)condensate	0.1g
polyethylene glycol 400	0.1g
water, dist. to make	100.0mL

### EXAMPLE 4

#### Viscous Antiseptic Prepping Fluid

This fluid is useful as a non-running, viscous antiseptic fluid for surgical prepping and dressing:

povidone-iodine containing 10% available iodine	10.0g
hydroxyethylcellulose	1.0g
glycerol	1.0g
nonylphenolethoxylate	0.25g
water, dist. to make	100.0mL

The hydroxyethylcellulose grades of suitable viscosity properties should be selected to give sufficient viscosity so that a free-flowing, sufficiently viscous film forming fluid is obtained which is able to accurately delineate the defined areas of skin to which it is applied.

### EXAMPLE 5

#### Antiseptic Spray Bandage

methyhydroxyethyicelluose	2.0g
---------------------------	------

- 14 -

ethanol	40.0mL
carmoisine (Food Red 3) dye solution	
1.0% w/v	0.1mL
water, dist. to make	100.0mL

5 The chlorhexidine digluconate was added after an aqueous solution of both polymers has been obtained. The solution was then coloured and the pH if necessary adjusted between 6.5-7.0

10 The methylhydroxyethylcellulose grades of suitable viscosity properties should be selected to give sufficient viscosity so that a free-flowing, sufficiently viscous film forming fluid is obtained which is able to accurately delineate the defined areas of skin to which it is applied.

#### EXAMPLE 6

##### 15 Protective Film (Invisible Glove)

This fluid is useful as a protective film under surgeons' gloves or for emergency operations in the field:

chlorhexidine acetate	0.5g
ter-polymer of vinyl acetate,	
20 vinyl propionate and crotonic acid	6.0g
ethanol	70.0mL
2-aminomethylpropanol	0.5g
water, dist. to make	100.0mL

25 The method of preparation was the same as in Example 2. The fluid is applied by wetting the complete hand and letting the solvent evaporate before putting on surgical gloves. In case of emergencies where no gloves are available, the procedure is repeated twice.

#### Example 7

##### 30 Antiseptic Dressing

This fluid is useful as an antiseptic fluid for certain light dermatological infections:

trichlorophenoxydiphenylether	0.2g
co-polymer of N-vinyl-2-pyrrolidinone:	
35 vinyl acetate, ratio 20:80	8.0g
nonionic lanolin derivative	70.0mL
water, dist. to make	100.0mL

The trichlorohydroxydiphenylether was dissolved in the ethanol prior to mixing with the copolymer. The water was added as the final step.

- 15 -

Example 8Antiseptic Skin Disinfectant and Dressing for VeterinaryApplication

5	Antarox VRO 20	5.0g
	Antarox CO 880	3.0g
	Tylopur MH 1000	2.0g
	water to make	100.0mL

10 The Antarox products were added to the solution of the Tylopur. The pH was then adjusted to 4.5.

Antarox VRO 20 and Antarox Co 880 are from GAF Corp USA, Tylopur MH is a methyl hydroxyethylcellulose available from Hoechst AG, W. Germany.

15

Example 9Film forming Teat Dip for Mastitis Prophylaxis

	Antarox VRO 20	2.0g
	Antarox Co 880	1.5g
	Tylopur MH 100	2.0g
20	glycerol	7.0g
	water to make	100.0mL

This fluid is manufactured as described in Example 8.

The pH is to adjusted to a pH 4 with phosphoric acid.

25

30

35

- 16 -

CLAIMS

1. A dual purpose antiseptic fluid comprising at least one bactericide and/or bacteristatic, at least one water soluble or water dispersible polymer and water.
2. A fluid as defined in claim 1, further comprising at least one water miscible, non-toxic, volatile liquid.
3. A fluid as defined in claim 1 or claim 2, further comprising at least one topical local anaesthetic.
4. A fluid as defined in any one of claims 1 to 3, wherein the bactericide and/or bacteristatic is chlorhexidine digluconate, cetyl trimethylammonium bromide, benzalkonium chloride, triclosan, hexachlorophene, tribromsalan, triclocarban, cloflucarban, an iodophor or a mixture of two or more thereof.
5. A fluid as defined in any one of claims 1 to 4, further comprising at least one moisturiser.
6. A fluid as defined in claim 5, wherein the moisturiser is glycerol, sorbitol, diethylene glycol, polyethylene glycol, or a nonionic lanoline derivative.
7. A fluid as defined in any one of claims 1 to 6, wherein the polymer is methylcellulose, ethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, carboxymethylcellulose and its alkali metal salts and partial salts with 2-aminomethylpropanol, diethylaminopropylamine and triisopropanolamine; copolymers of N-vinyl-2-pyrrolidinone with vinyl acetate, vinyl propionate, crotonic acid, long chain  $\alpha$ -olefins, alkylaminoacrylates and methacrylates; copolymers of vinyl acetate with crotonic acid; terpolymers of N-vinyl-2-pyrrolidinone with vinyl acetate and vinyl propionate, or with vinyl acetate and alkylaminoacrylates or methacrylates; quarternised copolymers of N-vinyl-2-pyrrolidinone and dimethylaminoethyl methacrylate;

- 17 -

copolymer, a N-vinyl-2-pyrrolidinone-long chain  $\alpha$ -olefin copolymer, a N-vinyl-2-pyrrolidinone-dimethylaminoethyl methacrylate copolymer, a poly (methyl vinyl eth r-maleic anhydride), or a quarternised copolymer of N-vinyl-2-pyrrolidinone and dimethylaminoethyl methacrylate.

9. A fluid as defined in any one of claims 1 to 8, wherein the bactericide is iodophor.

10. A fluid as defined in any one of claims 1 to 8, wherein the polymer has N-vinyl-2-pyrrolidinone as a component thereof and wherein the bactericide is formed by complexing iodine therewith.

11. A fluid as defined in any one of claims 1 to 10, contained in an apparatus which comprises a container for said fluid defining a reservoir, an applicator head in fluid communication therewith, fluid flow restricting means between said reservoir and said applicator head, first cap means associated with said container for filling with fluid and second cap means for said applicator head to prevent evaporation of fluid therefrom, wherein said applicator head comprises a resilient porous pad held in a dome shaped cap in contact with said fluid flow restricting means.

## AMENDED CLAIMS

[received by the International Bureau on 05 September 1986 (05.09.86);  
original claims 1,5,7,11 amended; 4 and 10 cancelled; others unchanged;  
claim 12 new (2 pages)]

1. A dual purpose antiseptic fluid comprising: at least one bactericide and/or bacteristat selected from chlorhexidine, chlorhexidine salts, cetyl tetramethylammonium bromide, benzalkonium chloride, triclosan, hexachlorophene, tribromsalan, triclocarban, cloflucarban, an iodophor or a mixture of two or more thereof; at least one water soluble or water dispersible film forming polymer and water in the form of a substantially aqueous solution characterised in that on application to skin surfaces and drying a water soluble film results.
2. A fluid as defined in claim 1, further comprising at least one water miscible, non-toxic, volatile liquid.
3. A fluid as defined in claim 1 or claim 2, further comprising at least one topical local anaesthetic.
5. A fluid as defined in any one of claims 1 to 3, further comprising at least one moisturiser.
6. A fluid as defined in claim 5, wherein the moisturiser is glycerol, sorbitol, diethylene, glycol, polyethylene, glycol, or a nonionic lanoline derivative.
7. A fluid as defined in any one of claims 1 to 3, 5 or 6, wherein the polymer is methylcellulose, ethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, carboxymethylcellulose and its alkali metal salts and partial salts with 2-aminomethylpropanol, diethylaminopropylamine and triisopropanolamine; copolymers of N-vinyl-2-pyrrolidinone with vinyl acetate, vinyl propionate, crotonic acid, long chain  $\alpha$ -olefins, alkylaminoacrylates and methacrylates; copolymers of vinyl acetate with crotonic acid; terpolymers of N-vinyl-2-pyrrolidinone with vinyl acetate and vinyl propionate, or with vinyl acetate and alkylaminoacrylates or methacrylates; quarternised copolymers of N-vinyl-2-pyrrolidinone and dimethylaminoethyl methacrylate; poly(methyl vinyl ether-maleic anhydride); and polymers having free carbonyl groups.
8. A fluid as defined in claim 7, wherein the polymer is carboxymethylcellulose, a vinyl acetate-crotonic acid copolymer, a vinyl acetate-vinyl propionate-crotonic acid terpolymer, a vinyl acetate-N-vinyl-2-pyrrolidinone copolymer, a ~~N-vinyl-2-pyrrolidinone-long chain  $\alpha$ -olefin copolymer, a~~ N-vinyl-2-pyrrolidinone-dimethylaminoethyl methacrylate copolymer, a poly(methyl vinyl ether-maleic anhydride), or a quarternised copolymer of N-vinyl-2-pyrrolidinone and dimethylaminoethyl methacrylate.

9. A fluid as defined in any one of claims 1 to 8, wherein the bactericide is an iodophor.

11. A fluid as defined in any one of claims 1 to 3 or 5 to 9, defining a reservoir, an applicator head in fluid communication therewith, fluid flow restricting means between said reservoir and said applicator head, first cap means associated with said container for filling with fluid and second cap means for said applicator head to prevent evaporation of fluid therefrom, wherein said applicator head comprises a resilient porous pad held in a dome shaped cap in contact with said fluid flow restricting means.

12. A fluid as defined in claim 9 wherein the iodophor is polyvinylpyrrolidinone.

ORIGINAL  
ONE SHEET

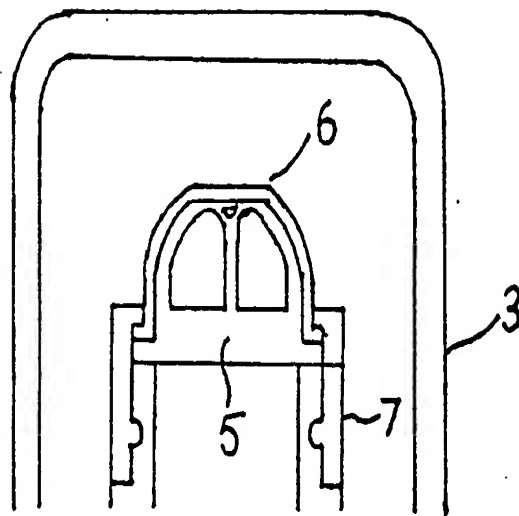
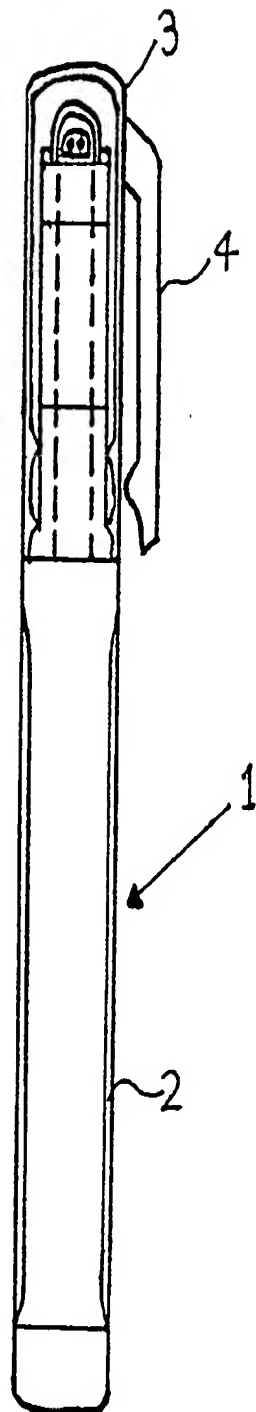


FIG. 2

FIG. 1

# INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 86/00068

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. <sup>4</sup> A61K 9/08, 9/10, A01N 25/02, 25/04, A61L 15/03		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC	A61K 9/00, 9/08, 9/10, A01N 25/02, 25/04, A61L 15/03	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
AU: IPC as above; Australian Classification 87.18.52, 87.18.56, 87.18.54		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT*</b>		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
X	AU,B, 16330/70 (442073) (SCHERICO LTD) 16 December 1971 (16.12.71)	1,3,4,5,6
X	AU,B, 40980/78 (527826) (VITAPHARM PHARMACEUTICAL PROPRIETARY) 1 May 1980 (01.05.80)	1,2,4,7
X	AU,A, 16369/83 (GAF CORPORATION) 5 April 1984 (05.04.84)	1,2,4,7,8,9,10
P,X	AU,A, 43241/85 (MINNESOTA MINING AND MANUFACTURING CO.) 12 December 1985 (12.12.85)	1,2,4,7,8,9,10
X	AU,B, 78262/81 (546450) (BAYER A.G.) 10 June 1982 (10.06.82)	1,2,6,7
X	AU,A, 16477/83 (MINNESOTA MINING AND MANUFACTURING CO.) 2 February 1984 (02.02.84)	1,4,9,10
X	AU,B, 36753/68 (418101) (BOOTS PURE DRUG CO. LIMITED) 30 October 1969 (30.10.69)	1,2,7,8
X	GB,A, 2134781 (DIOMED DEVELOPMENTS LTD) 22 August 1984 (22.08.84)	1,2,7
A	US,A, 4406884 (FAWZI et al) 27 September 1983 (27.09.83)	
A	US,A, 4439584 (GOULD et al) 27 March 1984 (27.03.84)	
<p>* Special categories of cited documents: **</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
24 June 1986 (24.06.86)	09 July 1986	
International Searching Authority	Signature of Authorized Officer	